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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	
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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/787,498	FRAZIER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Andrea M. Ragonese	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 April 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-28 and 30-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-28 and 30-54 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 16 March 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 6, 2005 has been entered.

### ***Response to Amendment***

2. The amendment filed on April 6, 2005 has been entered. Examiner acknowledges that **claim 22** has been amended. Subsequently, **claims 1-28 and 30-54** are under consideration.

### ***Response to Arguments***

3. Applicant's arguments filed April 6, 2005 have been fully considered but they are not persuasive.

With regard to the arguments in response to the 37 CFR 102(b) rejection of **claims 1-5, 8-11, 13-18, 20 and 21**, Applicant states, "Gerstel does not discloses a microneedle array device, as defined in **Claim 1**, wherein the microneedle array device comprises a plurality of hollow non-silicon microneedles on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface" (emphasis added by the Examiner). Applicant argues, "Gerstel discloses

projections **12** located on a surface **14** wherein the projections are perpendicular to the surface **14** on which they are located.” However, the Examiner respectfully disagrees.

First, as further explained hereinafter, Applicant has not explicitly recited in the original disclosure which element of the instant invention is considered the claimed limitation of “a substantially planar major surface.” Therefore, in a reasonably broad interpretation, the substrate of the prior art, shown at the arrow **10** in Figure 1, fully anticipates this claim limitation. The elements **16** and **14** are of unitary structure. Thus, element **16** is considered a major surface of the substrate **10**, and subsequently has been broadly and reasonably interpreted by the Examiner to be a “planar major surface” of the substrate **10**, on which the needles **12** are located and thus, from which the needles **12** “extend in a direction substantially parallel to the major surface.” Applicant, consequently, has failed to define structural limitations that define over the prior art. Thus, the rejection is reiterated below.

With regard to the arguments in response to the 37 CFR 102(b) rejection of claims **51-53**, Applicant states, “Miura does not disclose the limitations recited with respect to **Claim 51**.” Applicant argues, “Miura does not discloses a method...wherein the microneedles are formed on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface...” However, the Examiner respectfully disagrees.

Again, as further explained hereinafter (and previously stated above), Applicant has not explicitly recited in the original disclosure which element of the instant invention is considered the claimed limitation of “a substantially planar major surface.” Therefore,

in a reasonably broad interpretation, the method of the prior art fully anticipates this claim limitation. Miura et al. discloses a substrate **31** that has two dimensions. There are two surfaces: a length and thickness, both of which can be interpreted to be a "major surface." Thus, in a reasonably broad interpretation, the microneedles extend parallel to the thickness, which subsequently has been broadly and reasonably interpreted by the Examiner to be a "planar major surface" of the substrate on which the needles are located and thus, from which the needles "extend in a direction substantially parallel to the major surface." Applicant, consequently, has failed to define structural limitations that define over the prior art. Thus, the rejection is reiterated below.

4. Applicant's arguments with respect to **claims 12, 19, 22-28, 30-50** and **54** have been considered but are moot in view of the new ground(s) of rejection.

#### *Drawings*

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "plurality of input ports" of **claims 38** and **46** as well as the "plurality of microchannels" of **claims 42** and **48** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Terminal Disclaimers and Double Patenting Rejections***

6. Receipt is acknowledged of the terminal disclaimers filed on April 6, 2005 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent Nos. 5,871,158 and 5,876,582. These terminal disclaimers have been forwarded to the appropriate personnel for review and acceptance.

7. Until such time that the filed terminal disclaimers are reviewed and accepted, the double patenting rejections, as stated in the previous Office action, mail date December 6, 2004, will remain pending. A decision on the merits regarding these rejections will be made in a subsequent Office action from the Examiner.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **Claims 1-28, 30-32 and 51-54** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is reminded that no new matter may be entered in an amendment.

Regarding **claims 1-21 and 51-53**, Applicant submitted an amendment on August 26, 2003, which entered subject matter that was not supported by the originally filed disclosure. Specifically, the claim limitation, "a substantially planar major surface" was not adequately described in the original specification of the instant invention, and therefore, there is no evidence that Applicant possessed the invention at the time the application was filed. Therefore, this claim limitation is considered new matter and must be canceled from the claims.

Regarding **claims 22-28, 30-32 and 54**, Applicant submitted an amendment on April 6, 2005, which entered subject matter that was not supported by the originally filed disclosure. Specifically, the claim limitation, "a channel opening at an opposite distal end" was not adequately described in the original specification of the instant invention, and therefore, there is no evidence that Applicant possessed the invention at the time

the application was filed. Therefore, this claim limitation is considered new matter and must be canceled from the claims.

10. **Claims 40 and 48** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, **claims 40 and 48** recite a claim limitation, "plurality of microchannels" in a single microneedle/shaft. This claim limitation lacks an adequate description in the originally filed disclosure, including the drawings, to enable one of ordinary skill in the art to make and/or use the invention.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claims 1-5, 8-11, 13-18, 20, 21, 33-37 and 43-45** are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al. (US 3,964,482).

Regarding **claim 1**, in a reasonably broad interpretation, Gerstel et al. discloses a microneedle array device having a substrate **10**, as shown in Figure 1, with elements **16** and **14**, which are of unitary structure. Thus, element **16** is considered a major surface of the substrate **10**, and subsequently has been broadly and reasonably interpreted by the Examiner to be a "planar major surface" of the substrate **10**, on which

the needles **12** are located and thus, from which the needles **12** “extend in a direction substantially parallel to the major surface” (column 4, lines 23-35; column 6, lines 30-40; and column 8), as seen in Figures 1-6. Each of the microneedles **12** has a microchannel **11** therethrough that provides communication between at least one input port **32** at a proximal end of each of the microneedles **12** and at least one output port **18** at an opposite distal end that extends beyond an edge of the substrate **10** (columns 4-6).

Regarding **claim 2**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles each having a bottom wall, two side walls, and a top wall that define a microchannel, necessary of a hollow structure. Given a reasonably broad interpretation, even a tube can be considered having walls.

Regarding **claim 3**, Gerstel et al. discloses that as applied to **claim 2**, as well as, a bottom wall is formed at least partially on top of the major surface of the substrate and the side walls and top wall are formed around a removable molding material (column 8 and column 9).

Regarding **claim 4**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles that are in a two dimensional array, as seen in Figures 1-4.

Regarding **claim 5**, Gerstel et al. discloses that as applied to **claim 2**, as well as, microneedles that are in a three-dimensional array, as seen in Figure 2, where the device spans in 3 dimensions.

Regarding **claim 8**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles that are aligned substantially parallel to each other on the substrate, as seen in Figures 1-4.

Regarding **claim 9**, Gerstel et al. discloses that as applied to **claim 1**, as well as, a distal end of each microneedle that extends beyond the edge of the substrate a distance from about 10  $\mu\text{m}$  to about 100 mm (column 7, lines 60-67).

Regarding **claim 10**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles having a cross-sectional area in the range from about 25  $\mu\text{m}^2$  to about 5000  $\mu\text{m}^2$  (column 7, lines 52-55). A 15-40-gauge size falls within the range.

Regarding **claim 11**, Gerstel et al. discloses that as applied to **claim 1**, as well as, a length of each microneedle that is from about 0.05  $\mu\text{m}$  to about 5 mm, and the width of each microneedle is from about 0.05  $\mu\text{m}$  to about 1 mm (column 7, lines 40-67).

Regarding **claim 13**, Gerstel et al. discloses that as applied to **claim 1**, as well as, a substrate of a material selected from the group consisting of glass, semiconductor materials, metals, ceramics, plastics, and composites or combinations thereof (column 8, lines 30-60).

Regarding **claim 14**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles of a material selected from the group consisting of metals, plastics, ceramics, glass, carbon black, and composites or combinations thereof (column 8, lines 30-60).

Regarding **claim 15**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles comprise a metal material selected from the group consisting of

nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof (column 8, lines 30-60).

Regarding **claim 16**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles that can withstand flow rates of up to about 1.5 cc/sec.

Regarding **claim 17**, Gerstel et al. discloses that as applied to **claim 1**, as well as, a coupling channel member **16** that provides fluid communication between the microneedles.

Regarding **claim 18**, Gerstel et al. discloses that as applied to **claim 17**, as well as, a coupling channel member is composed of the same material as the microneedles.

Regarding **claim 20**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles have a plurality of input ports, as seen in Figures 1-4.

Regarding **claim 21**, Gerstel et al. discloses that as applied to **claim 1**, as well as, microneedles that have a plurality of output ports.

Regarding **claim 33**, Gerstel et al. discloses a microneedle device having a substrate **10**, as shown in Figure 1, having a substantially planar surface. The device has at least one single hollow non-silicon microneedle **12** on a planar surface of the substrate. Microneedle **12** has at least one microchannel **11** therethrough that provides communication between at least one input port **32** at a proximal end of the microneedle **12** and at least one output port **18** at an opposite distal end that extends beyond an edge of the substrate **10** (columns 4-6).

Regarding **claim 34**, Gerstel et al. discloses that as applied to **claim 33**, as well as, a distal end of the microneedle that extends beyond the edge of the substrate a distance from about 10  $\mu\text{m}$  to about 100 mm (column 7, lines 60-67).

Regarding **claim 35**, Gerstel et al. discloses that as applied to **claim 33**, as well as, the microneedle has a cross-sectional area in the range from about 25  $\mu\text{m}^2$  to about 5000  $\mu\text{m}^2$  (column 7, lines 52-55). A 15-40-gauge size falls within the range.

Regarding **claim 36**, Gerstel et al. discloses that as applied to **claim 33**, as well as, a substrate of a material selected from the group consisting of glass, semiconductor materials, metals, ceramics, plastics, and composites or combinations thereof (column 8, lines 30-60).

Regarding **claim 37**, Gerstel et al. discloses that as applied to **claim 33**, as well as, a microneedle comprising a metal material selected from the group consisting of nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof (column 8, lines 30-60).

Regarding **claim 43**, Gerstel et al. discloses a microneedle device having at least one single hollow elongated shaft **12** comprised of a non-silicon material. The shaft has at least one microchannel **11** therethrough as well as a proximal end and a distal end. The shaft **12** also has at least one input port **32** at a proximal end of the shaft **12** and at least one output port **18** at an opposite distal end (columns 4-6).

Regarding **claim 44**, Gerstel et al. discloses that as applied to **claim 43**, as well as, the microchannel has a cross-sectional area in the range from about 25  $\mu\text{m}^2$  to about 5000  $\mu\text{m}^2$  (column 7, lines 52-55). A 15-40-gauge size falls within the range.

Regarding **claim 45**, Gerstel et al. discloses that as applied to **claim 43**, as well as, the shaft comprises a metal material selected from the group consisting of nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof (column 8, lines 30-60).

13. **Claims 51-53** are rejected under 35 U.S.C. 102(b) as being anticipated by Miura et al. (US 4,728,392).

Regarding **claim 51**, Miura et al. discloses a method comprising:

providing a substrate **31** with a substantially planar major surface;

depositing a metal material **32** on a major surface to form one or more bottom walls for one or more microneedles/nozzles (column 6, lines 35-65);

coating a top surface of the one or more bottom walls with a photoresist layer **33** to a height corresponding to a selected inner height of a microchannel for the one or more microneedles;

depositing a metal material to form side walls and a top wall upon the one or more bottom walls and around the photoresist layer; and

removing the photoresist layer from the microchannel of the one or microneedles/nozzles (column 6, lines 35-65).

Miura et al. discloses a substrate **31** that has two dimensions. There are two surfaces: a length and thickness, both of which can be interpreted to be a "major surface." Thus, in a reasonably broad interpretation, the microneedles extend parallel to the thickness, which subsequently has been broadly and reasonably interpreted by the Examiner to be a "planar major surface" of the substrate on which the needles are

located and thus, from which the needles “extend in a direction substantially parallel to the major surface.”

Regarding **claim 52**, Miura et al. discloses that as applied to **claim 51**, as well as, metal material that is deposited by an electroplating process (column 6, lines 45-47).

Regarding **claim 53**, Miura et al. discloses that as applied to **claim 51**, as well as, a metal material that is selected from the group consisting of palladium, titanium, chromium, nickel, gold, copper, and alloys thereof (column 6, lines 43-50).

***Claim Rejections – 35 USC § 102 and 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. **Claims 22-28 and 30-32** are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Gerstel et al. (US 3,964,482).

Regarding **claim 22**, Gerstel et al. discloses a microneedle array device having a plurality of hollow non-silicon microneedles **12** having a microchannel **11** therethrough that provides communication between at least one input port **32** at a proximal end of each of the microneedles **12** and at least one channel opening **18** at an opposite distal end; and at least one structural support member **14** that interconnects the microneedles (column 4-8), as seen in Figures 1-4. Gerstel et al. discloses a cover **33** that is broadly and reasonably interpreted to be the "at least one second structural support member that interconnects the microneedles adjacent the distal end of the microneedles" (column 6, lines 55-65). Gerstel et al. discloses a device comprising all the limitations recited in **claim 22**, but does not explicitly recite an outlet port at the distal end of the microneedle. However, the use of an outlet port in combination with the end of a channel opening would be obvious, if not inherent, given the structure shown in Figures 1-4. As broadly and reasonably interpreted by the prior art drawings, Gerstel et al. discloses a device that would be obvious, if not inherent, to have both a channel

opening and an outlet port, in combination, at the distal end of a microneedle channel in order to control the amount of medication delivered from the channel opening.

Regarding **claim 23**, Gerstel et al. discloses that as applied to **claim 22**, as well as, microneedles each having a bottom wall, two side walls, and a top wall that define a microchannel, necessary of a hollow structure. Given a reasonably broad interpretation, even a tube can be considered having walls.

Regarding **claim 24**, Gerstel et al. discloses that as applied to **claim 22**, as well as, microneedles that are in a two dimensional array, as seen in Figures 1-4.

Regarding **claim 25**, Gerstel et al. discloses that as applied to **claim 22**, as well as, microneedles that are in a three-dimensional array, as seen in Figure 2, where the device spans in 3 dimensions.

Regarding **claim 26**, Gerstel et al. discloses that as applied to **claim 22**, as well as, microneedles of a material selected from the group consisting of metals, plastics, ceramics, glass, carbon black, and composites or combinations thereof (column 8, lines 30-60).

Regarding **claim 27**, Gerstel et al. discloses that as applied to **claim 22**, as well as, microneedles comprise a metal material selected from the group consisting of nickel, copper, gold, palladium, titanium, chromium, and alloys or combinations thereof (column 8, lines 30-60).

Regarding **claim 28**, Gerstel et al. discloses that as applied to **claim 22**, as well as, a coupling channel member **16** that provides fluid communication between the microneedles.

Regarding **claim 30**, Gerstel et al. discloses that as applied to **claim 22**, as well as, wherein the structural support members are fully capable of precisely controlling the penetration depth of the microneedles.

Regarding **claim 31**, Gerstel et al. discloses that as applied to **claim 22**, as well as, microneedles have a plurality of input ports, as seen in Figures 1-4.

Regarding **claim 32**, Gerstel et al. discloses that as applied to **claim 22**, as well as, microneedles that have a plurality of output ports.

***Claim Rejections - 35 USC § 103***

18. **Claims 6-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al. (US 3,964,482), as applied to **claims 1 and 5** above, in view of Ozbay et al. (US 5,406,573).

Regarding **claim 6**, Gerstel et al. discloses that as applied to **claim 5**. However, Gerstel et al. do not recite a three-dimensional array having a plurality of two-dimensional arrays with spacers therebetween. On the other hand, Ozbay et al. teaches arrays that are located on a major surface of a substrate (columns 12-19), as seen in Figure 1. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Gerstel et al. to include a three-dimensional array having a plurality of two-dimensional arrays with spacers in-between, as taught by Ozbay et al., for the purpose of ease of manufacture and transportation.

Regarding **claim 7**, Gerstel et al. as modified by Ozbay et al. discloses that as applied to **claim 6**. Further, it would be obvious to one with ordinary skill for the modification to have the three-dimensional array bonded together by a material selected

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from the group consisting of molding materials, polymeric adhesives, and combinations thereof.

19. **Claims 12, 19, 38-42, 46-50** and **54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al. (US 3,964,482), as applied to **claims 1, 22, 33** and **43** above.

Regarding **claim 12**, Gerstel et al. discloses that as applied to **claim 1**. However, Gerstel et al. do not explicitly recite a center-to-center spacing between individual microneedles that is from about 50  $\mu\text{m}$  to about 200  $\mu\text{m}$ . On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention to have the needles be spaced as claimed for the purpose of maximizing the amount of needles in a given space.

Regarding **claims 19 and 54**, Gerstel et al. discloses that as applied to **claims 1** and **22**. However, Gerstel et al. do not explicitly recite a pair of/plurality of structural support members that mechanically interconnect the microneedles. On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention of Gerstel et al. to include interconnects for the purpose of more precisely controlling penetration depth of the microneedles, as dependent upon the application.

Regarding **claims 38-40**, Gerstel et al. as modified discloses that as applied to **claim 33**. Further a microneedle that has a proximal end has a having a plurality of input ports, a plurality of output ports and a plurality of microchannels would further be obvious to one with ordinary skill in the art.

Regarding **claim 41**, Gerstel et al. discloses that as applied to **claim 33**, as well as, a structural support **14** that is fully capable of controlling the penetration depth.

Regarding **claim 42**, Gerstel et al. as modified discloses that as applied to **claim 41**, and a structural support that is adapted to mechanically fix the microneedle device to a surface that is penetrated by the microneedle is also within the scope of the invention.

Regarding **claim 46**, Gerstel et al. discloses that as applied to **claim 43**, as well as, microneedles have a plurality of input ports, as seen in Figures 1-4.

Regarding **claim 47**, Gerstel et al. discloses that as applied to **claim 43**, as well as, microneedles that have a plurality of output ports.

Regarding **claim 48**, Gerstel et al. discloses that as applied to **claim 43**, as well as, a plurality of microchannels **11**, as seen in Figures 1-4.

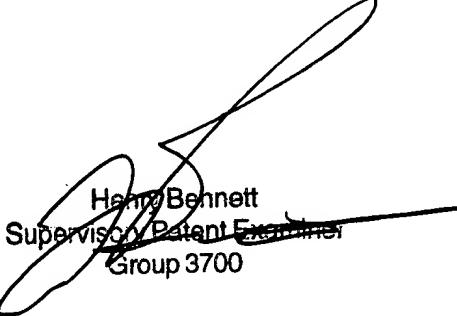
Regarding **claim 49**, Gerstel et al. discloses that as applied to **claim 43**, as well as, at least one structural support member **14** that is fully capable of precisely controlling the penetration depth of the microneedles, as seen in Figures 1-4. Given the structure, the needles cannot penetrate further than the member **14** permits.

Regarding **claim 50**, Gerstel et al. discloses that as applied to **claim 49**, as well as, a structural support that is fully capable of being adapted to mechanically fix the microneedle device to the surface that is penetrated by the elongated shaft, given the structure.

***Conclusion***

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.
21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR   
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